DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 15, 2014

Hogue Surgical, LLC
Mr. Roger S. Hogue, MD, RVT
Chief Executive Officer
7365 Kirkwood Court, North, Suite 350
Maple Grove, Minnesota 55369

Re: K140366
Trade/Device Name: Hogue Surgical EndlessFiber® Reusable Surgical Laser Fiber
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: July 24, 2014
Received: July 29, 2014

Dear Mr. Hogue:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, ″Misbranding by reference to premarket notification″ (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140366

Device Name
Hogue Surgical EndlessFiber® Reusable Surgical Laser Fiber

Indications for Use *(Describe)*
The Hogue Surgical EndlessFiber® SMA-BAR family of medical devices is intended for clinical use in laser surgery procedures for cutting, coagulating, or vaporizing in any soft tissue application for which compatible Nd:YAG, Ho:YAG, Diode, and KTP laser systems have been cleared for medical use, provided they are fitted with a launch port aperture compatible with the EndlessFiber® SMA 905 connector.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 7: 510(k) Summary

<table>
<tr><td>DATE</td><td>March 20, 2014</td></tr>
<tr><td>NAME OF FIRM</td><td>Hogue Surgical, LLC
7365 Kirkwood Ct. N., Suite 350
Maple Grove, MN 55369</td></tr>
<tr><td>510(k) CONTACT</td><td>Roger S. Hogue, MD, RVT (763) 424-8682</td></tr>
<tr><td>TRADE NAME</td><td>Hogue Surgical EndlessFiber® Reusable Surgical Laser Fiber
Model Number: HSEF-R-SMA-SMA-xxx-yyy</td></tr>
<tr><td>COMMON NAME</td><td>Laser Surgery Fiber Optic Delivery System</td></tr>
<tr><td>CLASSIFICATION</td><td>Classified by the General and Plastic Surgery Device Panel into Class II, under 21 CFR 878.4810</td></tr>
<tr><td>PRODUCT CODE</td><td>GEX</td></tr>
<tr><td>PREDICATE</td><td>K050738</td></tr>
<tr><td>DESCRIPTION</td><td>The Hogue Surgical EndlessFiber® Reusable Surgical Laser Fiber is a family of optical fibers that are terminated at one end with industry standard SMA 905 connectors. Each connector is fitted with a collar, a strain relief to the fiber, and a dust cover to protect the mechanically-cleaved fiber endfaces.</td></tr>
<tr><td>INDICATIONS FOR USE</td><td>The Hogue Surgical EndlessFiber® SMA-BAR family of medical devices is intended for clinical use in laser surgery procedures for cutting, coagulating, or vaporizing in any soft tissue application for which compatible Nd:YAG, Ho:YAG, Diode, and KTP laser systems have been cleared for medical use, provided they are fitted with a launch port aperture compatible with the EndlessFiber® SMA 905 connector.</td></tr>
<tr><td>TECHNOLOGICAL CHARACTERISTICS</td><td>The Hogue Surgical EndlessFiber® Reusable Surgical Laser Fiber utilizes industry-standard glass-core, double-clad, Tefzel®-coated optical fibers. It is terminated with a Hogue Surgical SMA-905 connector with adjustable ferrule. Each fiber endface is mechanically-cleaved to yield essentially optically-flat surfaces perpendicular to the fiber longitudinal axis. Each SMA connector has a strain relief to protect the optical fiber from inadvertent damage. Each SMA connector is fitted with a protective dust cover and cylindrical aluminum collar that may be used to manipulate the connector. The device is reusable and delivered non-sterile. Inspection of the fiber endfaces indicating contamination requires cleaning, stripping, cleaving, and re-inspection prior to reuse. A hex socket tool is available to simplify use with laser launch port connectors that are recessed.
<table>
<tr><th>Characteristic</th><th>K140366</th><th>K050738</th></tr>
<tr><td>Manufacturer</td><td>Hogue Surgical, LLC</td><td>FiberTech GmBH (Leoni Fiber Optics, Inc)</td></tr>
<tr><td>Indications for Use</td><td>“… cutting, coagulating, or vaporizing of soft tissue”</td><td>“… cutting, coagulating, or vaporizing of soft tissue”</td></tr>
<tr><td>Connector Termination</td><td>Special High Power SMA 905 Connector with Air-gap Well-Type Design</td><td>Special High Power SMA 905 Connector with Air-gap Well-Type Design</td></tr>
<tr><td>Ferrule Adjustability</td><td>Adjustable ferrule position relative to precision-cleaved proximal fiber endface with set screw to secure ferrule position relative to fiber</td><td>Non-adjustable, fixed ferrule position relative to mechanically-polished proximal fiber endface with adhesive used to secure ferrule position relative to fiber</td></tr>
<tr><td>Ferrule Design</td><td>Surgical Stainless with air-gap, well-type design</td><td>Surgical Stainless with air-gap, well-type design</td></tr>
<tr><td>Optical Fiber Manufacturer</td><td>CeramOptec®</td><td>Unknown</td></tr>
<tr><td>Nominal Wavelength</td><td>Suitable for 532nm up to 2200 nm</td><td>Suitable for 532nm up to 2200nm</td></tr>
<tr><td>Optical Fiber Core</td><td>Glass composition</td><td>Glass composition</td></tr>
<tr><td>Optical Fiber Primary Cladding</td><td>Fluorine Silica</td><td>Fluorine Silica</td></tr>
<tr><td>Optical Fiber Secondary Cladding</td><td>Hard Polymer</td><td>Hard Polymer</td></tr>
</table>
</td></tr>
</table>

	<table><tr><td>Optical Fiber Jacket</td><td>Tefzel® ETFE</td><td>Tefzel® ETFE</td></tr><tr><td>Inner Core Diameter (um)</td><td>365, 550, 600, 800, 940</td><td>365, 550, 600, 800, 940</td></tr><tr><td>Standard Length (m)</td><td>3.5</td><td>3.0</td></tr><tr><td>Optical Fiber Numerical Aperture</td><td>0.22</td><td>0.22</td></tr><tr><td>Connector Collar</td><td>Color-coded by fiber size</td><td>Color-coded by device family</td></tr><tr><td>Model Identification</td><td>Laser-inscribed on color-coded collar</td><td>Laser-inscribed on color-coded collar</td></tr><tr><td>Max Power into Air (W)</td><td>30</td><td>30</td></tr><tr><td>Protective Cap</td><td>Stainless Steel</td><td>Plastic</td></tr><tr><td>Sold As</td><td>Non-Sterile, reusable device</td><td>Sterile, reusable; and sterile disposable</td></tr><tr><td>Strain Relief Boot Specifics</td><td>Plastic Boot secured by friction fit</td><td>Plastic Boot secured by adhesive</td></tr><tr><td>Known technological differences</td><td>Special High Power SMA 905 Connector can be completely disassembled into its component parts; these differences do not raise safety or effectiveness concerns because the components can be inspected, repaired or replaced to ensure intended device performance</td><td>Special High Power SMA 905 Connector cannot be disassembled as its components are secured with adhesive</td></tr><tr><td>Proximal Fiber Endface</td><td>Mechanically cleaved, flat</td><td>Mechanically polished, flat</td></tr><tr><td>Distal Fiber Endface</td><td>Mechanically cleaved, flat</td><td>Mechanically cleaved, flat</td></tr></table> The only known technological differences between this device and its predicate are the optical connector design and the mechanical preparation of the proximal fiber endface (in the optical connector). Bench testing performance data demonstrates that the two types of device are comparable in their performance.
BASIS FOR SUBSTANTIAL EQUIVALENCE	Samples of this device and samples of its predicate, in their various sizes, have been compared experimentally for functional (optical transmission) performance. Using the SE flowchart (BB Memorandum #K86-3), the Hogue Surgical EndlessFiber® SMA-BAR family of medical devices has the same intended use and technological characteristics as the legally-marketed predicate (K050738). The device is no less safe or effective and performs as well as the predicate devices.
PERFORMANCE DATA	The device has been verified to possess the following safe handling characteristics as confirmed by bench testing @30W @30 minutes @1064nm discharging into air: (a) optical input attenuation of less than 10%; (b) SMA905 connection temperature rise of less than 10°F. The Hogue Surgical, LLC surgical laser delivery fiber operates in the same manner as the predicate device and performs with no differences as compared to the predicate device.